

## **REMARKS**

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed November 16, 2004. Claims 1 and 59-86 are pending. Claims 1, 67, 81 and 84 have been amended. Support for the amendments to the claims can be found in the specification and drawings as originally filed. No new matter has been added. Reconsideration and reexamination are respectfully requested.

### **Allowable Subject Matter**

Applicants thank the Examiner for indicating that claims 73, 74, 78, 82, 83 and 85 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Objection to the Specification**

The specification is objected to because the reference to an earlier application has not been updated. However, Applicants draw the Examiner's attention to the Amendment filed concurrently with a Petition to Claim Benefit Under 35 U.S.C. § 120 on September 24, 2004. The prior filed amendment and the above amendment to the specification regarding status of the earlier application overcome this objection.

### **Objections to the Claims**

Claim 67 is objected to for lacking antecedent basis. The claim has been amended to depend from claim 66 as suggested by the Examiner.

### **Rejections under 35 U.S.C. § 102**

Claims 1, 59, 61, 64, 66-69, 71, 75-77, 79-81 and 84 are rejected as being anticipated by Healy (US 4,757,817). Applicants respectfully traverse the rejection.

The device of Healy is an adhesive electrode pad for attaching an electrode to a patient's skin. See Abstract; column 3, lines 28-41; and column 4, lines 5-19.

Independent claims 1, 75, 81, and 84 recite in the preamble that the lead electrode assembly is implantable. Healy does not teach or suggest an implantable lead electrode assembly. The Examiner asserts that the preamble in the instant claims is merely an intended use. It appears to Applicants that this statement is a reference to the positioning of the defibrillator as subcutaneous. However, whether subcutaneously placed or not, an implantable

electrode is understood by one of skill in the art as having different requirements (i.e., biocompatibility, sealability, size, durability) than a non-implantable electrode.

Healy specifically teaches his adhesive pad for external use on a patient's skin. MPEP § 2111.02, under the heading PREAMBLE STATEMENTS RECITING PURPOSE OR INTENDED USE, quotes *In re Schreiber* 44 USPQ2d 1429 in stating that if "a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim." Applicants submit that the structure disclosed by Healy is unsuitable for, and therefore incapable of, performing the recited intended use of being implanted and used for electrical stimulation. Applying the recited standard, one must conclude the prior art structure does not "meet the claim".

With respect to the instant claims, Applicants submit that "the claim preamble is 'necessary to give life, meaning, and vitality' to the claim" and thus "the claim preamble should be construed as if in the balance of the claim." See MPEP § 2111.02, quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.* 51 USPQ2d 1161. Applicants submit that the recitation in the instant claims of the electrode assembly being implantable distinguishes the claimed device from the external electrode of Healy.

Moreover, the body of independent claims 1, 81, and 84, as amended, recite the electrode, backing layer, and fin (appendage) are adapted for implantation in a patient. Applicants submit that the claims recite a positive structural feature of the electrode assembly that is not found or suggested in Healy. As stated above, Healy specifically teaches his electrode assembly for attachment to a patient's skin. See column 3, lines 28-41. Healy requires a conductive jelly in order to provide an electrically conductive relationship between the electrode and the patient's skin. Healy also teaches an adhesive for adhering the electrode pad to the patient's skin. Applicants submit that the electrode, conductive jelly, and backing layer of Healy are not adapted for implantation in a patient. Furthermore, there is no motivation for one of ordinary skill in the art to modify the electrode assembly of Healy for implantation in a patient.

In light of the above remarks, it is believed that each of independent claims 1, 75, 81 and 84 along with dependent claims 59, 61, 64, 66-69, 71, 76-77, 79-80, 85 and 86 are patentable over the cited reference. Additionally, at least some of these claims include additional patentable subject matter that further distinguishes them from Healy, some of which were discussed in more

detail in the Amendment After Final dated January 14, 2005. As such, the Applicants respectfully request withdrawal of this rejection.

Claims 1, 59-62, 64, 68, 69, 71, 72, 75-77 and 79-81 are rejected as being anticipated by Bishay et al. (US 6,272,385). Applicants respectfully traverse the rejection.

Bishay et al. disclose an independently deployable sealed defibrillator electrode that is applied directly to the victim's chest and that is for use with an automatic or semi-automatic external defibrillator. See column 4, lines 1-7; Abstract; column 2, lines 62-66; column 3, lines 5-9; and Figures 2, 4A, and 4B.

As stated above with respect to the Healy reference, independent claims 1, 75 and 81 recite in the preamble that the lead electrode assembly is implantable. Bishay et al. do not teach or suggest an implantable lead electrode assembly, as claimed. Again, Applicants refer to the differences noted above including size, durability, biocompatibility, and the like that distinguish implantable electrodes from non-implantable electrodes. With specific reference to Bishay et al., Applicants note the size of the electrode as suggested in Figures 4A and 4B, which covers a large portion of the patient's pectoral region. Such a large electrode would not be considered "implantable". Applicants submit that the structure of Bishay et al.'s electrode is not capable of performing the intended use of being implanted, as is recited in the claims and therefore, as with Healy, does not meet the claims under the standard of MPEP § 2111.02 discussed above.

Additionally, as discussed above, independent claims 1, and 81, as amended, recite the electrode, backing layer, and fin (appendage) are adapted for implantation in a patient. Applicants submit that the claims recite a positive structural feature of the electrode assembly that is not found or suggested in Bishay et al. As stated above, Bishay et al. specifically teach their electrode assembly for attachment to a patient's skin. See column 4, lines 5-6. Bishay et al. require a conductive jelly in order to provide an electrically conductive relationship between the electrode and the patient's skin. Bishay et al. also teach an adhesive for adhering the electrode pad to the patient's skin. Applicants submit that the electrode, conductive jelly, and backing layer of Bishay et al. are not adapted for implantation in a patient. Furthermore, there is no motivation for one of ordinary skill in the art to modify the electrode assembly of Bishay et al. for implantation in a patient.

For at least these reasons, it is believed that each of independent claims 1, 75 and 81, along with dependent claims 59-62, 64, 68, 69, 71, 72, 76-77 and 79-80, are patentable over the cited reference. Additionally, at least some of these claims include additional patentable subject matter that further distinguishes them from Bishay et al., at least some of which were discussed in more detail in the Amendment After Final dated January 14, 2005. As such, the Applicants respectfully request withdrawal of this rejection.

**Rejections under 35 U.S.C. § 103**

Claims 62 and 63 are rejected as being unpatentable over Healy in view of Krasnow (US 3,828,766). Claims 69 and 86 are rejected as being unpatentable over Healy. It appears the Examiner intended to reject claims 69, 70, and 86, as it is claim 70 that recites silicone. Claim 65 is rejected as being unpatentable over Bishay et al. Applicants respectfully traverse these rejections.

Claims 62 and 63 are dependent from claim 1, and as indicated above, claim 1 is allowable over Healy, and Krasnow does not cure the deficiencies of Healy. Krasnow teaches a disposable adhesive electrode pad for attachment to a patient's skin. Krasnow thus does not provide any motivation or guidance for modifying Healy to achieve an implantable electrode assembly, as is recited in the claims. Krasnow again refers to and includes a gel pad used to provide an interface with the patient's skin. Therefore, Healy and Krasnow, either alone or in combination, fail to teach each and every element of the claims. Therefore, for at least these reasons, the Applicants respectfully request withdrawal of this rejection.

Claims 69 and 70 are also dependent upon claim 1, and claim 86 is dependent upon independent claim 84. As discussed above, independent claims 1 and 84 recite that the lead electrode assembly is implantable, and also recite that the electrode, backing layer, and fin (appendage) are adapted for implantation in a patient. As set forth above, Healy does not teach or suggest an implantable lead electrode assembly and therefore fails to teach each and every element of the claims. As such, for at least these reasons, the Applicants respectfully request withdrawal of this rejection.

Similarly, claim 65 is ultimately dependent upon claim 1, and as discussed above, claim 1 is allowable over Bishay et al. As discussed above, claim 1 recites that the lead electrode assembly is implantable, and also recites that the electrode, backing layer, and fin (appendage)

are adapted for implantation in a patient. Bishay et al. do not teach or suggest an implantable lead electrode assembly and therefore fail to teach each and every element of the claims, as discussed above. As such, for at least these reasons, the Applicants respectfully request withdrawal of this rejection.

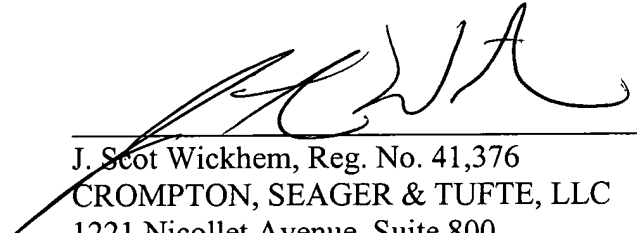
In light of the above remarks, withdrawal of the rejections, reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Gust H. Bardy et al.

By their Attorney,

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